

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA,)
ex rel.)
JULIE LONG,) Civil Action
)
Plaintiffs) No. 16-12182-FDS
)
)
vs.)
)
JANSSEN BIOTECH, INC.,)
Defendant)

BEFORE: CHIEF JUDGE F. DENNIS SAYLOR, IV

STATUS CONFERENCE CONDUCTED BY ZOOM

John Joseph Moakley United States Courthouse
1 Courthouse Way
Boston, MA 02210

March 14, 2025
2:00 p.m.

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15 **ALSO PRESENT: Thomas McCann, Esq.**

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PROCEEDINGS

THE CLERK: Court is now in session in the matter of United States vs. Janssen Biotech, Inc., Civil Action Number 16-12182.

Participants are reminded that photographing, recording or rebroadcasting of this hearing is prohibited, and it may result in sanctions.

Would counsel please identify themselves for the record, starting with the plaintiffs.

02:02PM MR. LEOPOLD: Good afternoon, your Honor, Ted Leopold on behalf of the relator plaintiff.

MR. RAZAVI: Poorad Razavi on behalf of relator plaintiff.

THE COURT: Good afternoon.

MR. PRESTON: Casey Preston on behalf of the relator.

THE COURT: Good afternoon.

MS. MARTIN: Diana Martin on behalf of the relator.

02:02PM MR. AZORSKY: Gary Azorsky on behalf of the relator.

THE COURT: Good afternoon.

MR. TORIC: Adnan Toric on behalf of the relator.

THE COURT: Good afternoon. All right. For Janssen.

1 MR. RAOFIELD: Good morning, your Honor,
2 Jason Raofield for Janssen. I think we also have on the
3 line my colleagues, Matthew Dunn, Nicholas Paston, and
4 Thomas McCann.

5 THE COURT: Good afternoon, all. This is a
6 status conference in this case. We're holding this by
7 video. I have pending and have had pending for some time
8 a couple of discovery motions, relator's motion for
9 in-camera review, and defendant's motion for a protective
02:03PM 10 order concerning a 30(b)(6) deposition.

11 I'm happy to -- if either of you want to briefly
12 address those, that's fine. I think I'm fairly familiar
13 with it at this point. I think at this point it's
14 important from my standpoint to get those opinions out and
15 to get this on track, but let me put that to one side for
16 the moment and ask where are we? What do we need to get
17 this case on track? And also is there anything about this
18 case that is affected by the First Circuit's *Regeneron*
19 decision that requires any attention on my end?

02:03PM 20 Mr. Leopold, I guess if you're taking the lead,
21 I'll start with you.

22 MR. LEOPOLD: Yes, your Honor, thank you. Again,
23 nice to see you. Thank you for your time today. Your
24 Honor, addressing a couple of issues that you raised. The
25 first two, of course, are the 30(b)(6) issue and the

1 matter we have of a protected privilege document log.

2 Just so your Honor knows, we have culled down,
3 and although there are a lot of documents that we are
4 contesting on the log, we've suggested maybe a sampling of
5 some of those documents with the Court to review or
6 magistrate judge or however the Court wants to do that to
7 make it hopefully easier for the Court, but those two
8 things are important.

9 As it relates to the *Regeneron* opinion --

02:04PM 10 THE COURT: Before I forget the thought, I would
11 be delighted to review a sample rather than 300 documents,
12 and is that something that has been formalized? In other
13 words, do you have an agreement that these -- actually you
14 can't have an agreement.

15 MR. LEOPOLD: Right.

16 THE COURT: Well --

17 MR. LEOPOLD: We don't have an agreement, your
18 Honor, and I'm not sure -- we tried to whittle down it as
19 much as we could for the ease of the Court. We can
02:05PM 20 certainly try to do that more because I understand the
21 burden that we put on the Court on those, but from our
22 perspective, of course, I'm sure the Court can appreciate
23 it's an important issue, so although we can whittle it
24 down, I think we want to give the Court a fair sampling of
25 the documents so that the Court can make a reasonable

1 review of them. I think that would be fair to everybody.

2 THE COURT: Okay. I'm sorry, you started talking
3 about Regeneron?

4 MR. LEOPOLD: Yes, your Honor. In light of the
5 Regeneron opinion, I sort of -- if the Court doesn't mind,
6 not that I want to throw it back to the Court, but, as the
7 Court knows, a little bit of the history of this case in
8 terms of the phase aspects that we have done discovery, in
9 light of the *Regeneron* opinion, I guess I'd really like to
02:05PM 10 ask the Court how the Court wants us to proceed at this
11 point in time, and by that I mean the discovery that we
12 have taken, although it was quote, unquote, "regional," it
13 really has, and I don't think there's a dispute about
14 this, really has informed us that the program of the ADS
15 managers was a national program, so we only really need
16 one aspects of future discovery for us to put on what I
17 would say a case going down on the avenue in *Regeneron* of
18 the self-certification aspect, which is where we believe
19 that we are going to pursue this matter, and we would need
02:06PM 20 some additional discovery.

21 And then the question becomes, A, does the Court
22 want to have more of a regional type of trial or want to
23 have in essence one case that we put on the national
24 aspect and the damages aspect? That's really where we're
25 at this point.

1 We have done all of the regional discovery, if
2 you will, that we believe that we need. We need some
3 additional information from Janssen in order to take care
4 of the expert issues, but we believe we are ready to go.
5 We'd like to get a trial date, and we can pursue this
6 following the avenues set forth in *Regeneron*.

7 THE COURT: Mr. Raofield.

8 MR. RAOFIELD: Yes, your Honor. So, first, to
9 respond to Mr. Leopold's comment in response to your
02:07PM 10 Honor's question about the in-camera review motion, I
11 apologize if I get anything wrong, but my understanding is
12 that I just want to make sure there is no ambiguity.

13 I think the 300 documents that your Honor
14 referred to was identified in their motion as a sample
15 that would potentially lead to then further review, and we
16 have not discussed or talked about a narrowing of that
17 sample group that the plaintiff proposed, so maybe that
18 was clear, but I just wanted to make sure that was clear.

19 THE COURT: It was not clear. All right.

02:07PM 20 MR. RAOFIELD: So, your Honor, the current
21 schedule that was entered by the Court, you know, with
22 agreement of the parties takes us through expert
23 discovery, all of which starts 30 days after the, you
24 know, it starts after we finish the 30(b)(6), which is
25 30 days after the Court's order on that issue, as your

1 Honor knows.

2 And the parties have conferred briefly just in
3 theory, you know, primarily about what a summary judgment
4 briefing schedule would look like for Phase I summary
5 judgment after expert discovery is closed.

6 And so we think that will take us through expert
7 discovery and summary judgment on sort of the current
8 schedule and the agreed upon briefing schedule that we've
9 talked about, haven't finalized, but we can do that and
02:08PM 10 then submit.

11 As your Honor knows, causation discovery was
12 stayed pending the *Regeneron* ruling. Janssen's position
13 throughout this case has been that relator would have to
14 prove but-for causation. Relator disagreed with that,
15 asked for, and ultimately there was a stay of the but-for,
16 you know, the causation discovery from practices in
17 particular pending a determination about whether but-for
18 causation would be required, and *Regeneron* says it is
19 required for claims under the 2010 amendment, and
02:09PM 20 relator's complaint does allege such claims.

21 So we had a meet and confer with relator, and
22 they told us three things: They told us, Number 1, that
23 even though *Regeneron* said but-for causation is required
24 for some of their claims, they're not seeking -- they've
25 decided not to seek, I think, third-party causation

1 discovery from the practices because if I understood what
2 they were saying, they thought they could prove some sort
3 of, you know, an AKS base claim given some sort of
4 negligence standard that I don't understand.

5 We have no idea why Regeneron would make evidence
6 from the practices irrelevant since the practices are
7 alleged to have accepted the kickback, but, obviously,
8 relator can make their own determination about that.

9 The second thing they told us is that they might
02:10PM 10 have a causation expert of some type. We're not sure what
11 that will be, and also that relator was interested in
12 setting a trial date at the end of Phase I summary
13 judgment.

14 Janssen's position, your Honor, is, and it sounds
15 like Mr. Leopold is raising that for consideration,
16 Janssen's position is there would be many problems setting
17 a trial date immediately after Phase I discovery.

18 I wasn't quite clear. Mr. Leopold mentioned that
19 maybe they do need some Phase II discovery, but that, of
02:10PM 20 course, was always the plan was that following Phase I
21 summary judgment, if the claims survive, we'd get a Phase
22 II discovery.

23 Relator alleged from the very beginning of the
24 case, your Honor, that there was a nationwide program but
25 Julie Long was obviously only a part of one state, she

1 operated in one state, and until now the case has been
2 focused on relator's allegations, but Janssen has always,
3 as your Honor knows, disputed those allegations, and
4 discovery has now profoundly undermined those allegations.

5 Relator herself confirmed under oath that she,
6 you know, despite operating as an ABS delivering the
7 alleged kickbacks for 15 years, she never thought she was
8 doing anything wrong, never thought she was violating the
9 law, never thought she was doing anything wrong, and she
02:11PM 10 said that was true even though she described herself as a
11 healthcare compliance officer at Janssen.

12 Relators now decided they're not even going to
13 seek discovery of the practices that allegedly received
14 the kickbacks, and I think it's important.

15 THE COURT: Let me stop you there because, you
16 know, if you go down this path and Mr. Leopold is going to
17 respond and you're going to respond to him, and it's kind
18 of like a mini summary judgment argument.

19 MR. RAOFIELD: Okay.

02:11PM 20 THE COURT: We'll get to these issues. Unless
21 someone convinces me, and I know Mr. Leopold has been
22 trying to convince for me for what feels like 10 years
23 now, must be less than that not but not much, to get off
24 my plan, which is Phase I phase discovery, a relatively
25 narrow subset, expert discovery, summary judgment, we see

1 what the case looks like. If the whole thing survives,
2 maybe we open it up to national discovery or not, and I
3 don't like setting a trial date until I know what the case
4 is going to look like, and I want to set a real trial
5 date, so, you know, is this going to be a one-day trial?
6 Is it going to be a 12-month trial?

7 Those are both jokes, but, you know, it's a lot
8 harder to schedule a two-week trial than a one-week trial,
9 a three-week trial than a two-week trial and so on, and if
02:12PM 10 we're going to have a trial, I do need to set it pretty
11 far out given my schedule and all of your schedules.

12 I'm not going to be able to turn on a dime on
13 this, but I do think we need to go through summary
14 judgment first and say, okay, what does this case look
15 like? And to get to summary judgment, we need to complete
16 discovery, and I'm sure that, you know, my -- I'm as much
17 to blame here as anyone for having this case kind of
18 bogged down, and I want to get it unbogged, and I want to
19 issue these two rulings, I want to complete fact discovery
02:13PM 20 on Phase I, I want to do experts if that's relevant to
21 summary judgment, it sounds like it is, I want to do
22 summary judgment, you know, boom, boom, boom, and what I'd
23 like to do is to revive the practice of seeing you every
24 30 days or so, you know, just to make sure that we're on
25 track and so I know what's happening at each stage of the

1 game.

2 I think, you know, as a practical matter, it's
3 hard for me to imagine I could set a trial date, you know,
4 quicker than let's say a year from now. I don't know. I
5 don't know what this thing is going to look like, I don't
6 know how big or small it is going to be, what the issues
7 are going to be, but for causation, you know, in the
8 actual *Regeneron* case where I did the District Court
9 ruling, one of the arguments made against it is we'd have
02:14PM 10 to have a parade, every single doctor from every single
11 practice would have to, you know, talk about his or her
12 prescribing practices to make that work.

13 I have no idea whether it's true or not, but it
14 could be true at some level and, you know, that would
15 lengthen things considerably, so, again, my plan, hope,
16 desire is get these two things off my desk. If I'm going
17 to do an in-camera review, I'm going to do it, and we'll
18 wrap up fact discovery on Phase I. It may be something
19 less than perfect and get into expert discovery, and then
02:15PM 20 you'll have an opportunity obviously to move for summary
21 judgment or partial summary judgment, you know, or however
22 it is you want to approach the case, and maybe some of it
23 gets whittled down, maybe not.

24 Usually along the way at least some things wind
25 up, you know, getting dropped, the claim for intentional

1 interference with prospective business relations, those
2 things have a way of falling by the wayside.

3 And, again, I think that's what I want to do. So
4 good news is I won't be Chief Judge after July, and so
5 I'll immediately remove 50 percent of my workload, so that
6 will give me more time to pay attention to my full-time
7 cases. Go ahead.

8 MR. LEOPOLD: Your Honor, may I?

9 THE COURT: Yes.

02:15PM 10 MR. LEOPOLD: That all sounds fine by us. I
11 guess where we're at at this point in time is we on the
12 plaintiff's side, not knowing what the summary judgment is
13 going to be, do not believe that we need any more factual
14 discovery.

15 As I mentioned, a little bit ago, we intend to
16 pursue this case on the false certification theory.

17 THE COURT: Other than whatever -- if I agree
18 with you that these were improperly withheld on privileged
19 grounds, there's going to be some follow-up, I assume, on
02:16PM 20 that.

21 MR. LEOPOLD: Right. I was going to say at this
22 point, depending on how the Court rules on the privilege
23 document, there may be some follow-up, on how the Court
24 rules on the 30(b)(6), there's going to be one or two
25 depositions taken there. Absent that, really the only

1 thing we, I guess, need to address is whether or not we
2 need to do any causation issues. We really don't, again,
3 that's not going to be our theory of the case if every
4 doctor has to be deposed, et cetera, so we only need to
5 know whether or not the defendant is going to move on
6 summary judgment on some sort of damages issue, which if
7 that's the case, we'd like to have what we consider sort
8 of this regression, it's a small piece of information we
9 would need from the defendants that is not a deposition,
02:17PM 10 it's just them getting us some data information.

11 Other than that, we're done. We would like to
12 get a schedule where they would have to file their summary
13 judgment within, I don't know, 60, 90 days, whatever it
14 may be, just so we can get it on schedule and move
15 forward.

16 THE COURT: I certainly think we would need to
17 set a schedule. I will add somewhat sardonically but
18 awfully close to the truth that from the time I was a
19 first-year associate, probably a law firm summer clerk
02:17PM 20 before that, every time someone says we just need a small
21 bit of discovery, just need a couple of things, it's never
22 quite played out like that, but, you know, and yes, I want
23 to set a timetable. I don't think I'm quite ready to do
24 it yet, but I need to rule on these motions, get that out
25 the door, see what comes from that. I don't know how many

1 experts we're going to have and on what topics but a
2 timetable that is adhered to within reason I think is
3 highly desirable and I would like to get to that point
4 quickly. I'm not sure I'm quite ready to do it today.

5 I've extended the fact discovery deadline
6 multiple times, and, you know, we do have a deadline
7 coming up, but I would like to move this from the very
8 back burner to the front burner.

9 MR. RAOFIELD: Your Honor, Jason Raofield. So
02:18PM 10 the Court may be aware of this, but just to make clear,
11 the schedule that was entered a month and a half ago or so
12 by agreement of the parties and that the Court entered,
13 that schedule as it stands, it's triggered off the Court
14 rulings on the 30(b)(6).

15 THE COURT: Yes. 30 plus 30 plus 30, yes.

16 MR. RAOFIELD: Exactly. And so that takes us
17 into probably around November, and then the parties, as I
18 mentioned, have started conferring, and we can easily
19 confer and set immediately after the experts a summary
02:19PM 20 judgment briefing schedule similarly tied off at the end
21 of that, and that would take us through summary judgment.
22 I just wanted to make clear the immediate schedule has
23 already been set.

24 THE COURT: Well, all right. And it may be that
25 that winds up being the schedule. It would be desirable

1 from my standpoint if instead of November that were
2 October or September. I don't know if that's realistic or
3 not, I just don't have a good enough handle on where we
4 are and what needs to be done, and the case has been
5 around for just a little while.

6 I don't think I had any gray hair when it
7 started, and we need this on a track toward some kind of
8 resolution. What I'd like to do is set a further status
9 for roughly mid-April. I'd like to keep meeting every
02:19PM 10 30 days. I want to get these two things off my plate so
11 you can all get going on that. I'll turn that around as
12 quickly as I can, and I apologize for not having done that
13 long ago, and if further discovery flows from that,
14 whether documents designated privileged or further
15 30(b)(6) or whatever, you know, so be it, but don't assume
16 I may not tighten the schedule because I might.

17 MR. LEOPOLD: Your Honor, just two housekeeping
18 matters, if I could. One is, and Mr. Preston may know
19 this, I just don't, but how would the Court like us to get
02:20PM 20 these documents to you?

21 THE COURT: First off, I need to rule whether I'm
22 going to do an in-camera review at all, and, if so, you
23 can do it however you want, I guess. You know, probably a
24 disk or something, I don't know, maybe some, you know,
25 in-camera under seal PDF might work, I don't know. It

1 depends on the volume and all of that.

2 MR. LEOPOLD: Okay. The other aspect is, and I'm
3 not saying it's going to be necessary, but the Court may
4 remember the causation issue for purposes of our phased
5 discovery has sort of been off to the side not knowing
6 what they're going to do on summary judgment, again, we
7 may not need to, but we sort of addressed this many, many,
8 a while ago at a hearing, that if something comes up in
9 summary judgment where we haven't done discovery, the
02:21PM 10 Court may be open if we make an appropriate motion to
11 allow us.

12 THE COURT: I'll be open to reason, I'll leave it
13 that way.

14 MR. LEOPOLD: That's what I wanted to raise.

15 THE COURT: Also just because you can take
16 discovery on something or that you haven't doesn't mean
17 I'll allow it. It kind of depends.

18 MR. LEOPOLD: Yes, sir.

19 THE COURT: One disadvantage of, again, I was a
02:21PM 20 young man when this case started, but I'm now getting
21 pretty old. I do remember the days when we had very
22 little discovery on a lot of things, criminal cases, none
23 at all, and it might not be as perfect as you want it to
24 be.

25 MR. LEOPOLD: I understand.

1 MR. RAOFIELD: Your Honor, can I just make one
2 comment?

3 THE COURT: Yes.

4 MR. RAOFIELD: Notwithstanding what I'm about to
5 say, since we're going to be having regular conferences, I
6 think we can address it at that point. This is the first
7 time I've heard -- I'm not really following what
8 Mr. Leopold has been describing. The causation discovery
9 that was stayed was very clearly stated as third-party
02:22PM 10 causation discovery, the doctor discovery, as we sometimes
11 refer to it.

12 THE COURT: Yes.

13 MR. RAOFIELD: I can't tell if Mr. Leopold is
14 talking about reopening discovery as to Janssen, but that
15 was decided by the Court that -- okay. He's shaking his
16 head no.

17 MR. PRESTON: Let me weigh in here, Ted. I think
18 though that, you know, Jason, what you're overlooking is
19 the discovery that we would be seeking would relate to
02:22PM 20 discovery that an expert needs in order to conduct a
21 regression analysis, and that likely requires discovery
22 of, you know, provision of the alleged kickbacks to
23 physicians nationwide in order to conduct the regression
24 analysis, so in order for us to present expert testimony
25 on causation, we do need some additional discovery that

1 would be from Janssen.

2 THE COURT: All right. I express no opinion
3 about whether you're going to get that or whether, you
4 know, a regression analysis on middle Pennsylvania or
5 Pennsylvania isn't good enough for these purposes. As far
6 as I'm concerned anyway, those issues are up in the air.

7 MR. PRESTON: And, your Honor, is that an issue
8 you want us to discuss at the next conference because I
9 think for our purposes, we'd like clarity on this issue so
02:23PM 10 we can have the expert to start working or we can start
11 working with counsel on obtaining the data that is needed
12 to conduct the regression analysis.

13 THE COURT: All right. If you think you need
14 something and you don't have it, it would be best to file
15 a motion. I don't want to do things on the fly. This is
16 way too complicated, you know, for me to do that. I
17 retain my view stubbornly that I wanted this to be not a
18 nationwide case with nationwide discovery, at least in
19 this phase until it is -- until we have tested some of
02:24PM 20 these claims and this narrower window, and we may get
21 there eventually, we may not, I don't know, but I know
22 plaintiffs have been seeking to expand this case,
23 defendants are seeking to narrow it, I want to keep it
24 reasonably narrow unless someone very compellingly
25 convinces me otherwise, not as a final decision but as a

1 practical matter of managing this thing.

2 MR. PRESTON: Understood, your Honor.

3 THE COURT: I made no decisions on anything. If
4 you want me to rule in some particular way, yes, you get
5 discovery, no, you don't, file a motion.

6 MR. PRESTON: Understood.

7 MR. LEOPOLD: Your Honor, if I can ask?

8 THE COURT: Yes.

9 MR. LEOPOLD: I'm clearly not asking for an
02:25PM 10 advisory opinion or anything of that sort, I'm just trying
11 to understand in terms of what Mr. Raofield had to say in
12 terms of our theory of the case in terms of either false
13 certification or but-for, I guess at the end of the day,
14 we'll respond to their summary judgment on what the
15 established case law is and go from there. I don't
16 understand -- I have a hard time understanding that we're
17 isolated to a but-for rule, and cases don't say that, but
18 I'm just trying to -- we've been up in the air a little
19 bit juggling what the law is, and it seems like we still
02:26PM 20 have a battle with the law. I'm not supposed to respond
21 to the summary judgment.

22 THE COURT: Unlike the benighted Third Circuit,
23 you know, the law is clear in this circuit, anyway, it's
24 but-for causation, so at least that has been established.

25 And when I say benighted Third Circuit, I mean a

1 circuit dominated by Eagles fans in many respects, which
2 is a problem. Yes, go ahead.

3 MR. RAOFIELD: I think, your Honor, it sounds
4 like there's some uncertainty on Mr. Leopold's part. I
5 will also say there's uncertainty on Janssen's part, but I
6 think what's clear is through the expert discovery
7 process, through the summary judgment briefing, everyone
8 is going to get a lot of clarity.

9 THE COURT: Well, hopefully that's true. Clarity
02:27PM 10 would be good, but we'll take it a step at a time.

11 Matt, can you give me a conference date?

12 THE CLERK: How about, Tuesday April 15th at
13 3:30?

14 THE COURT: Tuesday, April 15th at 3:30 by Zoom.
15 You can always appear in person if you want or we can do
16 it hybrid, but the default will be Zoom.

17 MR. LEOPOLD: Thank you.

18 MR. RAOFIELD: That works, your Honor, thank you.

19 THE COURT: All right. Let's do that then, and
02:27PM 20 we'll get these things out the door one way or the other,
21 and we'll take it from there.

22 MR. LEOPOLD: Thank you, your Honor. Thank you
23 for your time.

24 THE COURT: Thank you.
25

1 (Whereupon, the hearing was adjourned at
2 2:27 p.m.)

3 C E R T I F I C A T E

4
5 UNITED STATES DISTRICT COURT)
6 DISTRICT OF MASSACHUSETTS) ss.
7 CITY OF BOSTON)

8 I do hereby certify that the foregoing transcript,
9 Pages 1 through 22 inclusive, was recorded by me
10 stenographically at the time and place aforesaid in Civil
11 Action No. 16-12182-FDS, THE UNITED STATES OF AMERICA ex rel.
12 JULIE LONG vs. JANSSEN BIOTECH, INC., and thereafter by me
13 reduced to typewriting and is a true and accurate record of the
14 proceedings.

15 Dated March 20, 2025.

16 s/s Valerie A. O'Hara

17 _____
18 VALERIE A. O'HARA
19 OFFICIAL COURT REPORTER
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